REMARKS

1. The Amendments and the Support Therefor

Claim 18 is canceled, three new claims (23-25) have been added, and claim 14 has been amended to leave claims 1-15 and 19-22 in the application. Payment for any newly-submitted claims in excess of the amount previously paid for should accompany this Response, as per 37 CFR §1.16(b)-(d), with the fee due being calculated as follows:

FEE CALCULATION

For	Already Paid	No. Extra	Rate (**SMALL ENTITY**)	Fee (**SMALL ENTITY**)
Total Claims	21 - 20 =	0	x $26 =	$26
Independent Claims	3 - 4 =	0	x $110 =	$0
			Total:	$26

No new matter has been added by the amendments, wherein claim 14 is amended to address the §112(2) issues raised in the Office Action, and new claims 23-25 find support in (for example) page 9 lines 1-17.

2. Claims 19-22

Please note that claims 19-22, submitted with the April 29, 2009 Response, were not taken into account in the August 5, 2009 Office Action. Kindly take these claims into account in further examination.

3. Rejection of Claims 1-15 and 18 under 35 USC §112(1)

The rejection of claim 18 is mooted by claim 18's cancellation.

Kindly reconsider the rejections of claims 1-15, since one of ordinary skill can readily make and use the invention without undue experimentation. The rejections state that:

> The "formula" at page 7, lines 15-18 of Applicant's specification is called into question. Specifically, the formula requires a "factor of ambient compensation" and the specification establishes that the factor "may be between 0.1 and 0.23 degrees centigrade and refers to the increase in the subject's core body temperature". Such number appears to simply be a mythical number because it is beyond routine experimentation for one of ordinary skill in the art to determine how the factor is chosen. The logic behind exactly how the number is chosen is non-existent in the specification. The specification simply suggests that a number between 0.1 and 0.23 may be chosen and that is refers to an increase in temperature. Without explanation as to regarding how the number is chosen, what factors lead to such decision and how the

> factor refers to the increase in the subject's core body temperature, a skilled artisan would be required to perform undo experimentation to correctly or most accurately pick a number between 0.1 and 0.23. Factors that may influence the chosen factor of ambient compensation are not explained, such missing factors may include the user's height, weight, sex, initial hydration, etc. It not enabled how the factor works or how it is chosen, therefore, it is beyond routine experimentation of one of ordinary skill in the art and a skilled artisan would not be able to make use of the invention.

However, see page 9 lines 1-17 (corresponding to pars. [0062]-[0064] of US Publ'n. 2008/0234600):

> The calculation performed by the processor is carried out at regular intervals as follows:
>
> [(core body temperature current-core body temperature normal) x weight] /
> (factor of ambient compensation x 100)
>
> .... The factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subject's core body temperature for every percent loss of body weight, in temperate and hot climates respectively.

Consider:

- As noted above, the "factor of ambient compensation" is "valued between 0.1 and 0.23 degrees," with the lower and upper values being set "*in temperate and hot climates respectively*." Thus, an ordinary artisan could readily set the ambient compensation factor by using the 0.1 value at a presumed temperate climate value of (for example) 0 degrees C, and using the 0.23 value at a presumed hot climate value of (for example) 30 degrees C, and scaling the ambient compensation factor as appropriate for values therebetween in accordance with a simple linear interpolation:

$$\text{Ambient Compensation Factor} = 0.1 + \frac{0.23 - 0.1}{30 - 0}\ \text{Temp.}$$

  From there, if it turns out that the presumed "temperate" 0 degree temperature and the presumed "hot climate" 30 degree temperature do not yield the desired results, it would by no means require "undue experimentation" for the artisan to adjust the slope in the foregoing formula.

- Note that in any event, the "factor of ambient compensation" is just a constant divisor – and thus as a practical matter, *it merely serves as a constant scaling factor that adjusts the output up or down*. Thus, while an ambient compensation factor within the noted 0.1 and 0.23 range is preferred, one could just as well choose *any* nonzero number (though the noted range is preferred to obtain an output which has a reasonable number of digits for display). The

relevance / effect of the ambient compensation factor would be apparent to one of ordinary skill upon merely observing the formula. From there, it is a profoundly simple matter for the ordinary artisan to simply choose an ambient compensation factor which yields output within a desired range (having a desired number of digits) for any given ambient temperature.

- As to the issue of:

> Factors that may influence the chosen factor of ambient compensation are not explained, such missing factors may include the user's height, weight, sex, initial hydration, etc.

These are not relevant. So long as one makes and uses the invention as per the aforementioned formula, one need not take these factors into account, and the invention still works suitably well. The fact remains that an ordinary artisan who makes and uses the invention as per the written description will have an operable invention.

4. Rejection of Claims 1-9 and 11-13 under 35 USC §112(2)

Kindly reconsider and withdraw these rejections. As noted in the prior Response, all that 35 USC §112(2) requires is that an ordinary artisan must reasonably be able to determine what is included within the claims, and what is excluded by the claims, when the claims are read in light of the specification. As noted by the Court of Appeals for the Federal Circuit in *Miles Laboratories Inc. v. Shandon Inc.*, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993):

> The "distinctly claiming" requirement [of 35 USC §112(2)] means that the claims must have a clear and definite meaning when construed in the light of the complete patent document. ... Section 112 thus ensures definiteness of claim language. ... The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. ... If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more.

(Citations omitted.) Or, as simply stated by MPEP 2173.02, the claims must "provid[e] clear warning to others as to what constitutes infringement of the patent." Further, as noted in the foregoing quote, a claim must be read in light of its specification to determine whether it is definite. See also *Howmedica Osteonics Corp. v. Tranquil Prospects Ltd.*, 74 USPQ2d 1680, 1683 (Fed. Cir. 2005) ("[t]he definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claim when read in light of the specification"); MPEP 2173.02

("Definiteness of claim language must be analyzed, not in a vacuum, but in light of . . . . [t]he content of the particular application disclosure . . . .").

Here, we submit that it cannot reasonably be disputed that an ordinary artisan reading claims 1-9 and 11-13 would understand whether accused matter falls within or outside of the claims. Some of the claims may be broad, but breadth does not equal indefiniteness; see MPEP 2173.04. To illustrate, see claim 1:

> A hydration monitor comprising a temperature sensor for measuring a subject's core body temperature and a processor, the processor being arranged to accept measurements from the temperature sensor and calculate a hydration level in dependence on changes in the measured core body temperature.

It is exceedingly easy for an ordinary artisan to determine whether or not matter falls within or outside the claim: if one has a hydration monitor with a core temperature sensor, with the monitor's processor determining a hydration level in dependence on core temperature changes, the matter is infringing. If the recited features are not present, the claim is not infringed. Again, the claim may be broad, but it is in no way indefinite – its meaning is quite clear.

The rejection of claim 1 also seems to assert that the claim is indefinite because it lacks "essential elements":

> One having an ordinary skill in the art at would not know what is included with the claims and what is excluded by the claims, when the claims are read in light of the specification because essential elements of calculating hydration level have not be included in claim 1. A skilled artisan would find the bounds of the claim indefinite as it is not known if the limitations "subject's weight" and a "factor of ambient compensation" are included with claim 1 to provide a hydration level when the claim is read in light of the specification, because such limitations are required for calculating the hydration level.

However, as acknowledged in MPEP 2172.01 and surrounding sections, a §112(2) rejection on the basis of "unclaimed essential matter" is only appropriate where the claim is truly indefinite, i.e., where an ordinary artisan cannot determine what the claim covers. Otherwise, it is well settled that one may claim an invention as broadly as one wishes, so long as the claim is definite and otherwise meets the requirements of §112. (Whether the broad claim then meets the requirements of §102 and §103 is another issue.) See, e.g., *Carl Zeiss Stiftung v. Renishaw plc*, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991):

It has long been held, and we today reaffirm, that it is entirely consistent with the claim definiteness requirement of the second paragraph of section 112, to present "subcombination" claims, drawn to only one aspect or combination of elements of an invention that has utility separate and apart from other aspects of the invention. As one of our predecessor courts stated, "it is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter," as it is "entirely appropriate, and consistent with §112, to present claims to only [one] aspect." *Bendix Corp. v. United States*, 600 F.2d 1364, 1369, 220 Ct. Cl. 507, 514, 204 USPQ 617, 621 (1979).

See also *Reiffin v. Microsoft Corp.*, 54 USPQ2d 1915, 1918 (Fed. Cir. 2000):

Section 112 Para.2 instructs the applicant to "distinctly claim [] the subject matter which the applicant regards as his invention." This does not automatically require inclusion in every claim of every element that is part of the device or its operation.

It is standard for applicants to provide claims that vary in scope and in content, including some elements of a novel device or method, and omitting others. See Irving Kayton, 1 Patent Practice (6th ed.) 3.1, 3.3 (1995):

> [P]atent practitioners typically draft a series of claims approximating a spectrum of patent protection. . . . The first way in which a claim may be made narrower is by adding a limitation to it in the form of an additional element.

Claiming an invention in this manner does not raise an issue of compliance with Section 112 Para.1. Indeed, the "omitted element test" threatens this venerable practice, which is also summarized in Ernest B. Lipscomb, III, **[1919]** 3 Lipscomb's Walker on Patents 290-91 (1985):

> [A] claim may cover an invention embracing the entire process, machine, manufacture, or composition of matter which is described in the specification, or it may cover such sub-processes or such sub-combinations of the invention as are new, useful and patentable.

See, e.g., *Special Equipment Co. v. Coe*, 324 U.S. 370 (1945) (reversing the rejection of a sub-combination claim directed to the previously claimed invention less one element). While the specification must of course describe the claimed invention, it is well established that the claims need not include every component that is described in the specification. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 [128 USPQ 354] (1961) (There is "no legally recognizable or protected 'essential' element . . . in a combination patent.").
. . .

When the claim is supported by the patent's disclosure, is adequately distinguished from the prior art, and otherwise meets the statutory requirements of patentability, neither law nor policy requires that the claim contain all the elements described in the specification as part of the new machine or method.

Also *Rodime PLC v. Seagate Technology Inc.*, 50 USPQ2d 1429, 1434 (Fed. Cir. 1999) ("A claim need not claim every function of a working device. Rather, a claim may specify improvements in one function without claiming the entire machine with its many functions.")

The §112(2) rejections of claims 14-15 are addressed by the amendment to claim 14. The §112(2) rejection of claim 18 is mooted by its cancellation.

5. Rejection of Claims 1, 9-14 and 18 under 35 USC §103 in view of U.S. Patent 6,138,079 to *Putnam* and U.S. Patent 6,540,686 to *Heikkilaet*

As noted by the Office Action, *Putnam* estimates hydration using a modified MET (METabolic equivalent) scale, which is an approximation of how much oxygen an "average" person uses (and how much energy they burn) compared with their state at rest. *Putnam* modifies the conventional MET calculation as shown at column 6 lines 10-11, by incorporating multipliers for the person's weight, the surrounding ambient temperature, and the square of the surrounding relative humidity (see column 6 line 12 onward for examples). A divisor of 1450 is also used, but this is a constant scaling factor which is not varied. As the Office Action acknowledges, *Putnam* does not measure or use body temperature to estimate hydration; it simply relies on the person's entry of this data into the *Putnam* device to get the estimated hydration (see, e.g., Abstract).

Heikkilaet calculates the amount of energy burned by a body on the basis of a function using:

> at least one or more **heart rate parameters** to be measured from heart rate information are introduced as input parameters into the model. A heart rate parameter may be e.g. **heart rate, standard deviation of the heart rate, rate of change of the heart rate** or other such variable measurable from heart beats. Furthermore, at least one **physiological parameter** describing the physiology of the user is introduced as input information into the model. The physiological parameters include **height, weight, age and sex**. The model can be made more accurate by using one or more optional parameters as input parameters of the model. In a preferred model, the **amount of energy supplied to the body** is introduced as an input parameter into the model. The amount of supplied energy refers to energy that has been consumed by eating or drinking or administered e.g. through an injection. . . . . An optional input parameter is **body temperature**, which can be measured e.g. from the skin by a thermometer. Furthermore, an optional input parameter of the model is the **surrounding temperature**, which affects the metabolism level in the same way as the body's own temperature, i.e. the higher the temperature, the higher the metabolism level. The model may also use a person's **blood pressure** as an input parameter, the blood pressure affecting the metabolism such that high blood pressure corresponds with high metabolism level. In a preferred embodiment, the

> model uses the **amounts of respiratory gases**, i.e. oxygen and carbon dioxide, as optional input parameters.

(Column 3 lines 7-31; emphasis added.) The function for determining energy consumption is generically presented at column 6 lines 21-35. It is notable that *Heikkilaet* does not know the form or specifics of the function: these are determined by the *Heikkilaet* invention. Note column 3 lines 32-53, column 5 lines 19-23, and column 6 line 46 onward, noting how *Heikkilaet* uses a neural network to determine the strength/weight to be accorded to each of the foregoing parameters, and thereby calibrate the function defining the body's energy consumption. The body's energy consumption can be represented by glucose consumption (see column 5 lines 19-23 and column 6 lines 35-38), and thus glucose consumption can be monitored from the user's blood to help calibrate the function (column 6 lines 43-45).

The rejections are both factually and legally flawed. Initially, a factual error is made in the Office Action's assertion that:

> Specifically, Heikkilaet teaches measuring an initial core body temperature with a temperature sensor ("body temperature, which can be measured e.g. from the skin by a thermometer" col. 3,11. 19-21) and a subsequent core body temperature of the user with the temperature sensor and subtracting the initial core body temperature from the subsequent core body temperature as Heikkilaet teaches detecting changes in skin temperature ("rate of change of the heart rate or other such variable measurable from heart beats" col. 3, II. 4-7) using a processor (col. 4,11. 23-36).

Heikkilaet does not teach measurement of core body temperature – which can differ *significantly* from skin temperature depending on one's present circulatory state and the temperature of one's surroundings – nor is there any mention in *Heikkilaet* of subtracting prior and later temperatures. (Note that the cited column 3 lines 4-7 relates solely to *Heikkilaet*'s heart rate parameters.) If the Office believes these features to be present in *Heikkilaet*, kindly identify with particularity where these features are reviewed, as per 37 CFR §1.104(c)(2).

As for legal error, there is simply nothing in these references, or in the general knowledge in the art, that would truly lead one who has no knowledge of the claimed invention to conceive the claimed invention. As explained in MPEP 2142:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the

> examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant"s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts.

If this process is followed, with the claimed invention being placed out of mind and the prior art being objectively considered from the standpoint of an ordinary artisan, it cannot fairly be said that the ordinary artisan would contemplate or consider the claimed invention (in particular that of claims 10-11 and 14). *Putnam* seeks to estimate hydration, but relies on the user's manual entry of MET parameters, weight, ambient temperature, and relative humidity to do so. *Heikkilaet* seeks to measure energy consumption and relies on measured heart rate to do so, but beyond that, *Heikkilaet* simply offers a mere suggestion that parameters such as height, weight, age, sex, supplied energy (calorie / fat / carbohydrate intake), skin temperature, ambient temperature, blood pressure, and respiratory gas content *may* be relevant, with their relevance to be determined by a neural network. It is simply not seen how an ordinary artisan would contemplate the use of core body temperature changes to determine hydration, particularly where the art does not teach the use of core body temperature, nor changes in temperature, to estimate hydration or energy consumption. The rationale for the rejection basically reasons that one would be led by *Heikkilaet* to modify *Putnam* to obtain the claimed invention simply because *Heikkilaet* is "more advanced." However, an objective review of the prior art shows that this simply isn't true, particularly where *Heikkilaet doesn't even know which parameters are relevant to energy consumption and tries to rely on statistical processing to figure this out*. At most, the situation presents an "obvious to try" situation, as described in MPEP 2145, wherein the art simply suggests some huge number of potential approaches to try, with no indication as to which might be successful.

Regarding claim 11, the Office Action cites *In re Boesch* in contending that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to the factor of ambient compensation of Putnam, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

This is flawed for two reasons. Initially, the stated rationale for the rejection does not adequately reflect the holding of *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980), which stated that "discovery of an optimum value *of a result effective variable in a known process* is ordinarily within the skill of the art" (emphasis added). In other words, *Boesch* holds that it's within the capabilities of an ordinary artisan to tinker with the parameters of known processes to fine-tune the processes, which is not the situation here. Further, as noted in MPEP 2144.04, the Office may only pose an obviousness rejection based on a rationale in a prior court decision "if the facts in [the] prior legal decision are sufficiently similar to those in [the] application under examination", which is not the case here. The case bears no factual similarities to *Boesch*, wherein the quantities of certain metals in an alloy simply needed to be optimized to minimize electron vacancies in the alloy.

6. Rejection of Claims 2-8 and 15 under 35 USC §103 in view of U.S. Patent 6,138,079 to *Putnam*, U.S. Patent 6,540,686 to *Heikkilaet*, and U.S. Patent 5,381,796 to *Pompei*

These claims are unobvious for the same reasons as their parent claims. Further, *Pompei* is basically a common ear thermometer. If one places the claimed invention out of mind and objectively reviews *Pompei*, *Putnam*, and *Heikkilaet*, as required by MPEP 2142, it is seen that there is nothing that would lead an ordinary artisan to contemplate their combination to attain the claimed invention. This is particularly so where (1) *Putnam* does not take *any* measurements from the body, temperature or otherwise, to estimate hydration, and rather relies on user input, and (2) *Heikkilaet* only uses a heart rate monitor which is preferably provided as a belt or the like (see column 8 line 43 onward), and possibly a glucose meter (see column 6 lines 55-66). One reviewing these references would at most incorporate a temperature sensor into the *Heikkilaet* heart rate monitor or the glucose meter to measure skin temperature, particularly since (1) it's undesirable to install multiple separate sensors on a user during exercise, and (2) *Heikkilaet* only mentions use of skin temperature.

7. New Claims 23-25

New claims 23-25 simply enhance the unobviousness of their parent claims, since these claims plainly conflict with *Heikkilaet*'s use of heart rate to determine the body's energy consumption.

8. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

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